IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC. and UNITED STATES VAPING ASSOCIATION, INC.,	§	
Plaintiffs,	§	
	§	Civil Case No. 1:19-cv-531-LG-JCG
v.	§	
FOOD AND DRUG ADMINISTRATION; NORMAN E. "NED" SHARPLESS, M.D., in his official capacity as Acting Commissioner of Food and Drugs; and ALEX M. AZAR, II, in his official capacity as Secretary of Health and Human Services,	§	DECLARATORY AND INJUNCTIVE RELIEF REQUESTED
Defendants.	§	

PLAINTIFFS' MEMORANDUM IN SUPPORT
OF MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs Big Time Vapes, Inc., and United States Vaping Association, Inc., file this memorandum in support of their motion for a preliminary injunction.

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INTRODUCTION

Plaintiff Big Time Vapes, Inc., and many—if not all—of Plaintiff United States Vaping Association's (USVA's) members, are facing insurmountable compliance burdens, substantial loss of sales, and the imminent complete destruction of their businesses due to the Food and Drug Administration's regulation of the vapor industry under the Tobacco Control Act (TCA).[1] However, all of this regulation is premised upon a provision of the TCA that delegates legislative authority to the executive branch in violation of the separation of powers. "Time and again[,]" the Supreme Court has "reaffirmed the importance in our constitutional scheme of the separation of governmental powers into three coordinate branches," *Morrison v. Olson*, 487 U.S. 654, 693 (1988), and it "has not hesitated to enforce the principle of separation of powers … when its application has proved necessary for the decisions of cases or controversies properly before it." *Buckley v. Valeo*, 424 U.S. 1, 123 (1976) (per curiam).

Neither has the Fifth Circuit hesitated to enforce these bedrock principles. In *Collins v. Mnuchin*, discussing the separation of powers, the Court of Appeals noted that "[t]he Constitution's unique architecture is 'the central guarantee of a just government' and essential to protecting individual liberty." 896 F.3d 640, 659 (5th Cir. 2018) (quoting *Freytag v. C.I.R.*, 501 U.S. 868, 870 (1991)), *reinstated in part by* __ F.3d __, 2019 WL 4233612, *2, 22 (5th Cir. 2019) (en banc). In *Collins*, a panel held that the structure of the Federal Housing Finance Agency violated the separation of powers, and its holding and analysis was reinstated by the full Fifth Circuit following rehearing en banc. *Collins v. Mnuchin*, 2019 WL 4233612 at *22. The en banc Court vigorously endorsed the judiciary's duty to enforce the structural principles of the Constitution, reiterating, "[t]he warning that 'if we are to continue a government of limited

[1] Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) (the "Tobacco Control Act" or "TCA"), *codified at* 21 U.S.C. § 387 *et seq*.

powers, these agencies must themselves be regulated' remains fresh as ever." *Id.* at *13 (quoting *New York v. FERC*, 535 U.S. 1, 18 (2002)). In another recent case, a panel of the Fifth Circuit granted a stay against an order issued by an administrative law judge of the Federal Deposit Insurance Corporation, after concluding that the movant demonstrated a "strong showing" that he was likely to succeed on his separation of powers challenge under the Appointments Clause. *Burgess v. Federal Deposit Ins. Corp.*, 871 F.3d 297, 301 (5th Cir. 2017).

"Whether the statute delegates legislative power is a question for the courts[.]" *Whitman v. American Trucking Associations*, 531 U.S. 457, 472 (2001). While the Supreme Court has upheld broad delegations of authority, it has always required the statute to include *some* standard reflecting Congress's chosen policy. In the absence of such a standard—where there is no guidance for the exercise of discretion—it means the agency is legislating, rather than Congress, and the Constitution is violated. *Id.* at 474 (referring to *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935)). The TCA's deeming provision confers authority upon the Secretary of Health and Human Services to "deem" tobacco products to be subject to the TCA, with no standards or principles to check his discretion. The deeming provision is, therefore, invalid under extant Supreme Court precedent, and this Court should not hesitate to grant the preliminary relief required to forestall catastrophic and irreparable harm to Big Time Vapes and the USVA's members.

BACKGROUND

I. Tobacco Control Act of 2009

In 2009, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FD&C Act"), by passing the Tobacco Control Act.[2] The Act mandates that "[t]obacco products … shall be regulated by the Secretary [of Health and Human Services] under this subchapter and shall not be subject to the provisions of subchapter V." 21 U.S.C. § 387a. (Subchapter V of the FD&C Act governs "drugs" and "devices.").

"Tobacco product" is defined to mean:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1).

Various "tobacco products" were in widespread use when Congress enacted the TCA—including cigarettes, cigars, smokeless tobacco, pipe tobacco, and hookah. But Congress did not choose to impose the Act's requirements on all of them. Instead, the statute provides that "**[t]his chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.**" 21 U.S.C. § 387a(b). "Roll-your-own tobacco" is defined to mean "any tobacco product which … is suitable for use and likely to be offered to, or purchased by, consumers as tobacco *for making cigarettes*." 21 U.S.C. § 387(15) (emphasis added).

[2] The TCA comprises subchapter IX of the Food, Drug, and Cosmetic Act (FDCA), which is codified in chapter 9 of title 21 of the United States Code.

Therefore, Congress itself imposed the TCA only upon cigarettes and cigarette tobacco, and "smokeless tobacco," which is limited to "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." *Id.* § 387(18). Left unregulated were all other forms of tobacco products, including such widely used products as cigars (premium and all other varieties), pipe tobacco, and hookah.

While Congress *itself* declined to impose the TCA's requirements on anything other than cigarettes or "smokeless tobacco," it purported to vest the Secretary of Health and Human Services with the authority impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. § 387a(b).[3]

The TCA imposes a variety of regulatory requirements on tobacco products subject to it.

Many of the most onerous burdens apply to "tobacco product manufacturers," a term[4] that, as applied in the Deeming Rule,[5] captures the vast majority of "e-cigarette retail stores and vape establishments." 81 Fed. Reg. at 28,979. FDA explained that "establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly,

[3] While the statute delegates deeming authority to "the Secretary [of HHS]," through a staff manual, the Secretary sub-delegated this power to the FDA Commissioner. FDA Staff Manual Guide 1410.10. The FDA Commissioner, in turn, sub-delegated this power to the Associate Commissioner for Policy. FDA Staff Manual Guide 1410.21 (authorizing the Associate Commissioner for Policy to assume the FDA Commissioner's authority to issue "proposed and final regulations").

[4] A "tobacco product manufacturer" is "any person, including any repacker or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." 21 U.S.C. § 387(20).

[5] "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

are subject to the same legal requirements that apply to other tobacco product manufacturers." *Id.*

The Act requires each covered manufacturer, including Plaintiff Big Time Vapes and many of the businesses represented by the USVA, to provide FDA a list of all ingredients and compounds added to its products, as well as any and all documentation pertaining to the products' health and related effects. 21 U.S.C. § 387d(a)-(b). The Act also requires manufacturers to register their places of business and their product listing with the agency. *Id.* § 387e. As discussed below, Plaintiff Big Time Vapes and the USVA's "manufacturer" members have complied with these requirements.

The Act also prohibits, among other things, the marketing of any covered "new tobacco product" without the FDA's approval, unless the product is grandfathered. *Id.* § 387j. The effect of this provision is that any covered tobacco product that was "not commercially marketed in the United States as of February 15, 2007" is banned from the marketplace without prior FDA approval. *See id.* § 387j(a).

There are two main pathways for FDA approval to market a "new tobacco product" covered by the TCA.

The less onerous pathway is to demonstrate that the new product is "substantially equivalent" to a product that was being commercially marketed in the United States on the February 2007 grandfather date. 21 U.S.C. § 387j(b). Substantial equivalence is demonstrated if the product "(i) has the same characteristics[6] of the predicate tobacco product; or (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information … that demonstrates that it is not appropriate to regulate the product …

[6] "Characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." 21 U.S.C. § 387j(a)(3)(B).

because the product does not raise different questions of public health." *Id.* § 387j(a)(3)(A). If the FDA concludes that the new product is substantially equivalent to the predicate product, it must issue an order allowing the product to be commercially marketed. *Id.* § 387j(c).

If the sponsor of a covered new product cannot invoke the substantial equivalence pathway because there was no predicate product on the market as of February 15, 2007, it must seek FDA approval through a "premarket tobacco application," sometimes referred to as a "PMTA."[7] This process requires the development and submission of substantial amounts of data, *see* 21 U.S.C. § 387j(b), as discussed further below.

The TCA requires the FDA either approve or deny a premarket review application within 180 days. 21 U.S.C. § 387j(c)(1)(A).

Failure to comply with the above-described provisions can result in a variety of serious consequences for manufacturers and retailers, including designation of one's products as misbranded or adulterated, *see* 21 U.S.C. §§ 387b, 387c, which in turn can trigger substantial civil penalties and imprisonment, 21 U.S.C. §§ 331, 333, as well as seizure of the offending products, 21 U.S.C. § 334.

II. Electronic Nicotine Delivery Systems (ENDS)

Vapor devices, also known as "electronic cigarettes," "e-cigarettes," or "electronic nicotine delivery systems (ENDS)," are handheld electronic devices used to heat and aerosolize a liquid mixture ("e-liquid") that includes flavoring and various levels of liquid nicotine, including zero nicotine. Once the liquid is aerosolized, the user inhales the "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without setting any tobacco on fire.

[7] *See* **Exhibit 1**, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* at 1 (Jun. 2019), https://www.fda.gov/media/127853/download. All referenced exhibits are fully incorporated herein.

Vapor devices come in "closed" or "open" systems. In a so-called "closed system," either the device itself or interchangeable pods or cartridges intended for use with that device come pre-filled with a particular type of e-liquid. *See* Exhibit 1 at 6 (definition of "E-cigarette"). In a so-called "open system," the device will not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device's e-liquid reservoir, or "tank," with the e-liquid and nicotine level of his or her choice. *Id.*

Former FDA Commissioner Scott Gottlieb, M.D., recognized that "what primarily causes death and disease from tobacco use isn't the nicotine" but "the act of lighting tobacco on fire to free that drug for inhalation," and "E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products." **Exhibit 2**, U.S. FOOD AND DRUG ADMINISTRATION, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 12, 2018); *see also id.* ("While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills people.").

III. The Deeming Rule

a. Deeming Rule issued

FDA published the Deeming Rule in the Federal Register on May 10, 2016. In the Deeming Rule, FDA exercised its authority under 21 U.S.C. § 387a(b), decreeing that it "deems all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under chapter IX" of the FD&C Act. 81 Fed. Reg. 28,976 (emphasis added). FDA explained the breadth of the Rule:

> Products that meet the statutory definition of "tobacco products" include currently marketed products such as dissolvables not already regulated by FDA, gels,

> waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.
>
> In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of "tobacco product," except accessories of such newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule.

81 Fed. Reg. 28,976.[8]

Application of the TCA to ENDS (and all other newly-deemed products) imposed certain obligations and restrictions upon the regulated community effective as of August 8, 2016. These include the requirement that any ENDS manufacturer, or retail establishment "mixing or preparing e-liquids or creating or modifying" ENDS devices for direct sale to consumers, register as "manufacturers" under the TCA and submit a list of all distinct products (including each distinct flavor/nicotine combination), and list all ingredients. *See* Deeming Rule, 81 Fed. Reg. at 29046.[9] The industry was also frozen as of the effective date of the Deeming Rule, in that "manufacturers" were permitted to continue marketing those product variations that were on the market as of the effective date of the Rule (pending timely submission of PMTAs), but could not introduce new variations. *Id.* at 28,978. FDA also imposed an immediate prohibition on the sale of any covered tobacco products to individuals under age 18, and required all product labels and

[8] Plaintiffs note the acronym "ENDS"—short for "electronic nicotine delivery systems" and deployed by FDA in the Deeming Rule—can be misleading, given that many persons who vape cease using nicotine blends at at all, and vape only the flavors. Nonetheless, Plaintiffs utilize the term interchangeably herein with "vaping" products.

[9] Other provisions of the TCA prohibit the sale or distribution of products bearing 'modified risk' descriptions (such as 'light,' 'low,' or 'mild') without FDA approval (subject to a separate "Modified Risk" approval process), and a prohibition on distribution of free samples. *See* Deeming Rule, 81 Fed. Reg. at 28,976.

advertising to prominently state: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

b. Premarket Review requirements under the TCA and shifting compliance deadlines.

The TCA also would have authorized FDA to halt sales of newly-deemed products until the TCA-required premarket review applications were processed and approved. *See* 21 U.S.C. § 387b (finding a tobacco product is "adulterated" if it is required to have a premarket review order but does not have one); *id.* § 331(a) (making it unlawful to introduce an adulterated tobacco product into interstate commerce). But as part of the Deeming Rule, FDA opted to implement the premarket review requirement more gradually, establishing a "staggered initial compliance period":

> [M]anufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order.

81 Fed. Reg. at 28978.

Because ENDS products are effectively ineligible for grandfathering or the "substantial equivalence" pathway, the FDA acknowledged that "nearly all ENDS products will be subject to premarket review," and the FDA candidly predicted "considerable product consolidation and [market] exit" for ENDS products. Regulatory Impact Analysis, AR 23,912-24,067 ("RIA"). This is because any variation, however slight, of any ingredient or component of either an e-liquid or an ENDS delivery device, such as variations in flavor, nicotine content, or quantity, would render the product a unique "new tobacco product" as defined in the TCA, *see* Exhibit 1 at 18-19, and therefore require its own unique premarket review application, *see* **Exhibit 4**, U.S.

FOOD AND DRUG ADMINISTRATION, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50566, 50573 (Sept. 25, 2019) ("Proposed Final PMTA Rule") (discussing proposed final definition of "new tobacco product").

FDA itself estimated that an initial premarket review application for e-liquids would cost between $181,686 and $2,014,120 per application, and applications for delivery devices it estimated would cost between $285,656 and $2,622,224 per application. U.S. FOOD AND DRUG ADMINISTRATION, Final Regulatory Impact Analysis (2016) (RIA), AR 23,998 (Table 11a), AR 24,001-02 (Table 12a).

Under the "staggered compliance policy," a manufacturer submitting a premarket review application was initially required to do so by August 8, 2018—24 months after the Rule became effective. *Id.* at 28,977-78 (describing compliance periods for the different pathways). FDA stated that it would then allow an additional 12-month period for review and approval of the PMTA before enforcement would commence, and would defer enforcement even further on a case-by-case basis. *Id.* at 28,978 ("However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.").

FDA subsequently extended the compliance deadlines. First, in May 2017, it extended the deadlines outlined in the Deeming Rule by three months.[10] Then, in August 2017, FDA announced another extension applying "only to compliance deadlines relating to premarket review requirements." **Exhibit 3**, U.S. FOOD AND DRUG ADMINISTRATION, *Extension of*

[10] U.S. FOOD AND DRUG ADMINISTRATION, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* (May 2017).

Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) ("August 2017 Guidance"). The August 2017 Guidance amended the FDA's prior compliance approach in substantive ways.

For example, whereas the Deeming Rule's "staggered compliance schedule" set out different deadlines for submission of applications by *application type* (substantial equivalence, exception to substantial equivalence, or premarket review), the August 2017 Guidance distinguished between *product type*. The deadline for any type of application regarding a newly deemed combustible tobacco product was established as August 8, 2021, and the deadline for any type of application for a noncombustible product was established as August 8, 2022. *See August 2017 Guidance* at 3, 8.

Additionally, the August 2017 Guidance "revis[ed] the compliance policy relating to the period after FDA receipt" of product applications. *Id.* at 3. In the Deeming Rule, FDA had established a 12-month compliance period for FDA review. The August 2017 Guidance reverted to a less definite compliance period pending review of submitted applications. *Id.* ("Under this new compliance policy, there will be a continued compliance period pending review of [marketing] applications … [t]his compliance period will continue until the agency renders a decision on an application … or the application is withdrawn.").

However, FDA has now been ordered by the federal district court for the District of Maryland to severely accelerate the compliance deadlines. In *American Academy of Pediatrics v. Food and Drug Administration*, the district court held that the FDA had failed to abide by the Administrative Procedures Act's notice and comment requirements in issuing the August 2017 Guidance. 379 F. Supp. 3d 461 (D. Md. 2019). The district court granted summary judgment

for the plaintiffs and ordered the parties to submit briefing as to the appropriate remedy for the violation of the APA.

After the parties' remedy briefs, in a subsequent order issued July 12, 2019, the District Court for the District of Maryland vacated FDA's August 2017 Guidance, and ordered as follows:

> 1. [T]he FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed within 10 months of the date of this Memorandum Opinion and Order;
>
> 2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
>
> 3. New Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application;
>
> 4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

American Academy of Pediatrics v. Food and Drug Administration, No. 8:18-cv-00883-PWG, 2019 WL 3067492, at *7 (D. Md. Jul. 12, 2019).

In other words, rather than allowing premarket review applications to be submitted for ENDS products by August 2022, FDA has been ordered to require their submission a full *twenty-seven months earlier*, by May 2020.[11] This severely accelerates the period within which Plaintiffs and others similarly situated are expected to prepare and file the complex PMTAs that even the FDA acknowledges are prohibitively expensive, and predicted would prompt "considerable product consolidation and [market] exit." RIA, AR 23,989-90 (FDA itself

[11] No formal order effectuating the court-mandated deadlines has yet been promulgated by FDA, as the Maryland court held that such guidance will be subject to the APA's notice and comment requirements. *See* 2019 WL 3067492, at *1 (indicating that while FDA need not effectuate the court's order through a formal rulemaking, it must do so through guidance following the notice and comment period).

assuming that "54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids [would] not submit a marketing application and will exit the market after the initial compliance period … ends.").

c. Premarket Review Application (PMTA) Particulars

As noted above, *one* of the consequences of "deeming" ENDS products to be subject to the TCA is the imposition of the TCA's premarket review provisions. For every "[n]ew tobacco product" subject to the TCA that was not on the market as of February 15, 2007 (and for grandfathered products that were modified after that date), Section 910 of the FD&C Act requires obtaining a "marketing authorization order" from FDA permitting the marketing of such products before they can be sold legally in the United States. *See* 21 U.S.C. § 387j. Unlike cigarettes, which were grandfathered and therefore exempt from the PMTA process, ENDS products must submit a PMTA and receive FDA authorization. *Id.* § 387j(a)(2)(A) ("[a]n order under subsection (c)(1)(A)(i) for a new tobacco product is required unless" the product qualifies under the SE pathway or is exempt from the SE pathway).

i. FDA explains for years that more time is required to develop "rules of the road" for ENDS PMTAs, before abruptly changing tune in June 2019 and suggesting a 10-month PMTA deadline before substantive requirements are even proposed.

The content requirements for a PMTA are stated in broad terms in the TCA itself 21 U.S.C. § 387j(b)(1)). Yet the specific requirements for ENDS PMTAs were not elaborated for years after the Deeming Rule was announced.

On June 28, 2017, in a speech announcing the FDA's comprehensive tobacco regulation plan, then-Commissioner Scott Gottlieb, M.D., acknowledged that FDA did not yet have the proper regulations in place for ENDS products, stating: "One area of emphasis will be to make sure we have the foundational regulatory architecture to ensure proper oversight of ENDS ….

Part of this will be developing regulations that we have not yet pursued because the Agency's tobacco program itself is so new."[12] Elaborating on this, the FDA stated in an official release that it

> plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs), Modified Risk Tobacco Product (MRTP) applications and reports to demonstrate Substantial Equivalence (SE). The FDA also plans to finalize guidance on how it intends to review PMTAs for ENDS.[13]

The following month, FDA issued the August 2017 Guidance extending the initial PMTA submission deadline for ENDS products to August 2022. Presumably, FDA extended the ENDS deadline by four full years because it was aware that it would take a significant amount of time for its still "so new" tobacco center to produce the "foundational rules" necessary to guide industry, and that it would take a significant amount of time for manufacturers to comply with those rules after they were finally disclosed. Then, for the next two years, Commissioner Gottlieb continued to emphasize the necessity of FDA taking the time necessary to develop the "foundational regulations" that would govern the PMTA process.

On November 3, 2017, Gottlieb stated that "[t]he foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate."[14]

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[12] **Exhibit 17**, FDA Comm'r S. Gottlieb, *Protecting American Families: Comprehensive Plan for Nicotine and Tobacco* (Jul. 28, 2017), at https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.

[13] U.S. FOOD AND DRUG ADMINISTRATION, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (Jun. 27, 2017) (emphasis added).

[14] FDA Comm'r S. Gottlieb, *Remarks at the National Press Club* (Nov. 3, 2017), at https://www.fda.gov/news-events/speeches-fda-officials/remarks-national-press-club-11032017.

Again, in a press release on March 15, 2018, then-Commissioner Gottlieb stated:

> For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of both novel nicotine delivery products such as e-cigarettes and traditional tobacco products will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximize any public health benefits and minimize their harms. This will be achieved through our ongoing regulatory work to develop several foundational rules, guidances, product standards and other regulations.
>
> …
>
> Finally, we also plan to take new steps to make sure that our policies and processes for the regulation of tobacco products are efficient and predictable, and consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We're committed to making sure that we have transparent regulatory policies and best practices in place to maximize our public health impact. To these ends, we plan to issue a series of foundational rules and guidance documents that will delineate key requirements of the regulatory process, such as the demonstration of substantial equivalence and the submission of applications for new tobacco products.[15]

Then again, on August 2, 2018, FDA released a statement that "foundational proposed rules" are needed "regarding the basic rules of the road, *especially when it comes to what's expected in premarket applications*."[16]

And again in February 2019, then-Commissioner Gottlieb, in sworn testimony before Congress, defended and affirmed that extending the PMTA deadline to August 2022 was

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[15] U.S. FOOD AND DRUG ADMINISTRATION, *Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels* (Mar. 14, 2018) (emphasis added), at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking.

[16] U.S. FOOD AND DRUG ADMINISTRATION, *Advancing Tobacco Regulation to Protect Children and Families: Update & New Initiatives from the FDA on the Anniversary of the Tobacco Control Act & FDA's Comprehensive Plan for Nicotine* (Aug. 2, 2018) (emphasis added), at https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-tobacco-regulation-protect-children-and-families-updates-and-new-initiatives-fda.

necessary "to give [FDA] the time to put in place the implementing regulations and guidance that would … provide the rules of the road for how to effectively traverse the PMTA process[.]"[17]

Thus, as recently as February of this year, the FDA Commissioner noted the absence of any implementing regulation governing PMTAs for ENDS, and that neither FDA, nor any industry stakeholder, knew "the rules of the road" for the PMTA process.

A few months later, in July 2019, the Maryland district court issued its order accelerating the PMTA submission deadline to May 2020.

ii. *Tentative* PMTA technical requirements

In June 2019, the FDA finally released a finalized (in a manner of speaking) ENDS PMTA Guidance for Industry. Exhibit 1. Despite being issued three years after the "draft guidance" of May 2016, this updated Guidance for Industry is, like the initial "draft guidance," expressly nonbinding. Every page contains a bolded disclaimer at the top stating: "***Contains Nonbinding Recommendations***." The first page includes a further disclaimer, enclosed in a box, prominently warning: "This guidance represents the current thinking of the [FDA] on this topic. It does not establish any rights for any person and is not binding on FDA or the public." *Id.* at 1. This nonbinding guidance—itself only a summary—runs 52 pages.

Completing a PMTA requires a comprehensive assessment of each new vapor product, including evaluations of the short- and long-term human health effects of the product on the population. This requires reviews of existing scientific literature, extensive product testing, toxicological studies and analysis, stability testing, materials testing, environmental assessments, and clinical studies of human subjects regarding various aspects of the use and effects of the

[17] *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2020: Hearings Before a Subcomm. of the H. Comm. on Appropriations*, 116th Cong. 35 (2019) (statement of FDA Comm'r S. Gottlieb).

product on both the user and non-users of each product. *See, generally*, Exhibit 1. Every requirement of the PMTA must be separately satisfied with respect to every variant of a product: "FDA considers each ENDS product with a differing flavor variant and/or nicotine strength to be a different product." *Id.* at 18-19.

Two months later—and *less than eight months* before the radically accelerated May 11, 2020 submission deadline—FDA finally released a *proposed* final rule establishing the actual requirements for PMTAs. Exhibit 4. The onerous burdens imposed by this process are illustrated by a review of just *some* representative requirements.

For example, one central component of a PMTA is the requirement to state all "constituents" of the particular product, including "harmful or potentially harmful constituents" (HPHCs), and conduct rigorous and varied tests for them. Exhibit 4, 84 Fed. Reg. at 50585. FDA writes that

> [p]roposed 1114.7(i)(1)(v) would require a full statement of the constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction products from leaching or aging. FDA considers constituents to be properties of the new tobacco product, a full statement of which is required to be in a PMTA by section 910(b)(1)(B) of the FD&C Act. The constituents contained within, and delivered from, the product can be detected through constituent testing on the product. The constituent testing should reflect the various conditions under which consumers may use the products (e.g., light use, typical use, and heavy use) and the types of products that consumers are likely to use in conjunction with the product. For example, an open (refillable) e-cigarette should be tested with a variety of e-liquids that consumers are likely to consume using the e-cigarette. The report of constituent testing must be conducted in the manner required by, and include all information that is specified in, proposed 1114.7(i)(1)(v), including the full test data.

Id. at 50585.

While it seems logical that the first step in even attempting to satisfy this "constituent" testing requirement would be to *identify the list of HPHCs for which FDA requires testing*

results, that detail still has not been resolved. FDA's initial draft PMTA guidance for ENDS issued in May 2016 listed 29 HPHCs. When the final (but still nonbinding) Guidance was issued in June 2019, eight of those HPHCs were removed and eleven new HPHCs (benzyl acetate, butyraldehyde, ethyl acetate, furfural, glycidol, isoamyl acetate, isobutyl acetate, methyl acetate, N-butanol, priopionic acid, and propylene oxide) were added. *Cf.* May 2016 Guidance at 26-27 *with* Exhibit 1 at 28-29. Then, on August 5, 2019, FDA published notice in the federal register seeking comments on whether an additional two substances never before identified in either version of the draft ENDS guidance—acetic acid and acetoin—should also be included in the list of HPHCs for ENDS. 84 Fed. Reg. 38032 (Aug. 5, 2019); *see also* Proposed Final PMTA Rule, 84 Fed. Reg. at 50585 (discussing evolving list of HPHCs).

As another example, under "Health risk investigations,"

> FDA interprets … the Act to include the effect of the product and its label, labeling, and advertising on tobacco use behavior and tobacco use topography because use behavior and topography are directly related to levels of exposure of HPHCs, which, in turn, impacts health risks. For example, changes in tobacco product use behavior and topography that result in more frequent or intense use of the product will result in greater exposure to HPHCs and may result in increased health risks. Aspects of a product that could result in more frequent or intense use compared to currently marketed products can include differences in the appeal and design of the product, including ingredients; flavors; alteration in the amount or delivery of nicotine; … the effort required to inhale, or the density of the smoke, vapor, or aerosol; or other changes which similarly affect user behavior (e.g., ventilation, filter density).
>
> [The] proposed [rule] would require a PMTA to contain full reports of investigations into the abuse liability of the new tobacco product that are published or known to, or which should reasonably be known to the applicant. … [I]f a PMTA does not contain substantive information regarding the abuse liability of a new tobacco product, FDA may refuse to file the application. This means where there is no published information regarding the abuse liability or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation and include a full report of the results in its PMTA for filing.

Proposed Final PMTA Rule, 84 Fed. Reg. at 50604. FDA helpfully notes that "[t]he 'standard' abuse liability study is a double-blind, placebo-controlled, within-subject study comparing several doses of a new product to a comparator product with a known abuse liability," and elaborates on proposed aspects of such a study. *Id.* FDA then warns that if it "lacks sufficient information regarding the potential abuse liability of the new tobacco product, it intends to issue a no marketing order for the new tobacco product." *Id.*

"Abuse liability" is just one of four categories of "health risk investigations" required under the proposed rule, and for each category, FDA warns that the applicant is expected to "conduct its own investigation" if there is no applicable study already available, and that FDA may refuse to file a PMTA lacking sufficient information. *Id.* at 50605.

The Proposed Final PMTA Rule goes on for dozens of pages; the foregoing are only two examples offered to illustrate what a PMTA require—merely to be accepted for filing. This snapshot elucidates the substantial costs of preparing and submitting a PMTA that FDA itself estimated in its Regulatory Impact Analysis accompanying the Deeming Rule, which estimates FDA reiterates again in the proposed rule. 84 Fed. Reg. at 50568.

IV. Imminent Ban on Flavored E-Liquids (Other than Tobacco Flavors)

On September 11, 2019, the Executive branch announced another abrupt policy change with respect to flavored ENDS products. This policy change was announced in a press conference at the White House, with President Trump joined by Defendants Azar and Sharpless. As stated in the FDA's News Release:

> "The Trump Administration is making it clear that we intend to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities," said [HHS] Secretary Alex Azar. "We will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."

Exhibit 5, FDA, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019). Defendant Azar explained that "with the President's support, the [FDA] intends to finalize a guidance document that would commence enforcement to require that all flavors, other than tobacco flavor, would be removed from the market." **Exhibit 6**, WhiteHouse.gov, *Remarks by President Trump in Meeting on E-Cigarettes* (Sept. 11, 2019). Azar stated that he expects the "final guidance that would announce all the parameters around the enforcement policy" to be issued in "several weeks," followed by "about a 30-day delayed effective date, as is customary with FDA's good guidance practices. And, at that point, all flavored e-cigarettes, other than tobacco flavor, would have to be removed from the market." *Id.* at 10. Azar represented that tobacco-flavored products could remain on the market and would be required to submit any PMTAs by May 2020, and PMTAs for other flavored products could be submitted as well, but those products would be off the market in the interim. *Id.*

An FDA statement issued September 20, 2019 states again that the Agency "intend[s] to finalize [this] compliance policy in the coming weeks[.]" U.S. FOOD AND DRUG ADMINISTRATION, *FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products* (Sept. 20, 2019). Acting Director Sharpless testified to the same effect in a Congressional hearing September 25.[18]

[18] **Exhibit 18**, *Sounding the Alarm: The Public Health Threats of E-Cigarettes: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. (Sept. 25, 2019) (prepared remarks of Acting Comm'r of Food & Drugs Norman E. Sharpless, M.D.), available at https://www.fda.gov/news-events/press-announcements/remarks-prepared-testimony-us-house-energy-and-commerce-subcommittee-fda-regulation-electronic.

V. Impact on the Plaintiffs

a. Impact of PMTA requirements

Plaintiff Big Time Vapes, Inc., and every other e-liquid "manufacturer," is faced with the curious requirement that they conduct a whole series of expensive clinical studies for each product—both of product constituents and the product's effect on users and nonusers—to be submitted to FDA roughly seven months from now, despite the fact that FDA has not even determined what "constituents" must be tested, the tests cannot possibly be conducted in a timely manner, and the PMTA rules are not even final. The FDA itself estimates the cost will be between $181,686 and $2,014,120 *per e-liquid application*, RIA, AR 23,998 (Table 11a), AR 24,001-02 (Table 12a), and a PMTA is required for *each* variation of *each* product.

While there is no final rule governing the requirements or process and no final list of constituents required to be tested, the TCA nonetheless requires FDA to refuse to accept for filing an incomplete PMTA (including one that lacks required testing results), and FDA has repeatedly warned that it will do so. Exhibit 1 at 10; Exhibit 4 (Proposed Final PMTA Rule), at 50577 (discussing "Application Submission"), 50604-05 (testing requirements). If a complete PMTA is not accepted for filing by FDA by the May 2020 deadline, the manufacturer's products will be considered "adulterated" and subject to enforcement. *Id.* at 50569.

This looming deadline requires each vape shop qualifying as a "manufacturer" to either make whatever effort it possibly can to submit a PMTA for even a single product, knowing it will nonetheless fall short, or simply plan to wind down its business by the deadline. Plaintiff USVA represents exclusively small businesses in the vapor industry. **Exhibit 15** (Decl. of USVA). USVA currently has 53 members and continues to grow. *Id.* Smax International, LLC, is a member with comparatively more resources than the rest. While Smax "cannot even be sure

what tests we are supposed to run in order to file a complete or satisfactory PMTA," it "engaged attorneys at a well-regarded law firm in California to look into beginning preparations for PMTAs." **Exhibit 7** (Decl. of Tim Roberts) ¶7a. The attorneys contacted several labs to inquire as to availability and schedule for testing e-liquid constituents, but the "labs estimated tests would require twelve months." *Id.* ¶7b. Therefore, "[e]ven if [Smax] were to start testing now, there is not enough time to complete the tests before the current May 2020" deadline, "much less to complete them in time to get the results and summaries prepared and presented to the law firm or other consultants required to assist with preparing and submitting the PMTAs to FDA." *Id.* ¶7c.

Given this reality, "the only realistic option" anybody sees "would be to pay for lawyers and consultants to help prepare whatever limited tests and documents we could assemble and submit a PMTA for a single product by the deadline, and hope that either we win in litigation or the rules are changed to be more realistic." **Exhibit 8** (Decl. of Mega Vape LLC) ¶6d; *see also* **Exhibit 9** (Decl. of Big Time Vapes) ¶6c (same); **Exhibit 10** (Decl. of CJ Vapors LLC) ¶5e.

Moreover, all of the above comments regarding attempting to submit a single PMTA recognize that, due to PMTA cost alone, every manufacturer would have to drastically reduce its product line. Exhibit 7 (Smax) ¶7d; Exhibit 9 (Big Time Vapes) ¶6b; Exhibit 8 (Mega Vape) ¶6c; Exhibit 10 (CJ Vapors) ¶5d.

b. Impact of imminent flavor enforcement policy

Several of the USVA's members submitted declarations attesting to the importance of flavors in the vapor industry. For example, Brad Bennett of Mega Vape (TX) attests that, two weeks after he began vaping, he tried a cigarette for the first time again, and "it tasted awful." Exhibit 8 ¶2. Mr. Bennett states that 90-95% of his customers vape only non-tobacco-flavored

products, and that "very soon after a person switches from traditional cigarettes to vaping, their sense of taste and smell is restored, and they come to hate the flavor of tobacco." *Id.* ¶4. *See also* Exhibit 9 ¶2; Exhibit 12 ¶2; Exhibit 10 (CJ Vapors LLC) ¶3 ("90% of E-liquid sales come from flavored products," and "I am worried that without flavors many of our customers would return to smoking.").

The Secretary's announced plans to "remove[] from the market" all flavored ENDS products other than tobacco flavors will devastate manufacturers and retail-only vape shops. Plaintiffs submit declarations of several members reflecting that flavored products in flavors other than tobacco, as a rule, comprise between 90% and 98% of vape shop sales, and affirming that his or her business "would be forced to try to sell off inventory before the ban becomes effective and close the business." Exhibit 8 ¶7a; Exhibit 9 ¶7a; Exhibit 10 ¶6a; Exhibit 11 ¶6a; Exhibit 12 ¶5a; Exhibit 13 ¶7a; Exhibit 7 8a; *see also* Exhibit 8 (Mega Vape LLC stating that non-tobacco flavored products comprise 95% of e-liquid sales and 75% of "total company sales (including hardware, etc.)," "[b]ut if the flavors are banned, then the customers will not need to buy the hardware either"). Desertwind Vapors (TX) would have to lay off all five employees, as would Mega Vape LLC (eight employees in TX), Magnolia Vapes (twelve employees in MS), Big Time Vapes LLC (six employees in MS), Smax International LLC (six to ten of its fifteen employees in CO), Perfect Alternatives LLC (nine employees in CO), and CJ Vapors LLC (five employees in VA and WV).[19] Winding down these businesses would have to begin even *before* the effective date of the revised flavor policy, because these businesses would have to make

[19] Exhibits 7-13. Smax International may be able to stay in business, due to its overseas sales, but would lose approximately $60,000 of its monthly revenues of $90,000-$120,000 attributable to U.S. customers (comprising 50%-67% of monthly revenue). Exhibit 7 ¶5.

certain decisions immediately upon announcement of the policy, such as whether they could risk placing another order for inventory. Exhibit 7 ¶8a.

These members affirmed further financial consequences that would follow closing their businesses.

Juan Benavides (Desertwind Vapors, TX) would default on Desertwind's commercial lease, of which he is a personal guarantor, and, in light of this and other debt held by Desertwind, "would have to file for personal bankruptcy." Exhibit 13 ¶7c. He would also lose the value of the $210,000 invested in the business since inception.

Step Jones (XOXO Vapor Bar, TX) would default on his three-year commercial lease, be unable to repay $56,000 in other business debt, and would lose his only source of income other than social security, which is not sufficient to support him. He would be "unable to pay [his] mortgage, car insurance, car payments, and most of [his] bills," and would file for bankruptcy. Exhibit 11 ¶6d. He would also lose the $250,000 invested in the business since inception. *Id.*

Casey Adams (CJ Vapors LLC, VA and WV) would lose the only source of personal income for he and his wife, and, unable to continue paying rent, would default on the remaining $160,000 liability on his commercial lease. Exhibit 10 ¶6. He would have to declare bankruptcy, as he has personally guaranteed approximately $80,000 in outstanding loans owed by CJ Vapors LLC. *Id.* ¶6e.

Belinda Dudziak (Big Time Vapes, MS) would lose her sole source of income while trying to support a dependent child and pay her mortgage, and fears losing the more than $100,000 she has invested toward purchasing and maintaining her building. Exhibit 9.

James Jefcoat (Magnolia Vapes, MS) would lose his sole source of income (gross sales of $900,000 in 2018) and have to seek other work, and would lose the value of the $250,000 invested in the business. Exhibit 12.

Perfect Alternatives, LLC (CO) would remain liable on $362,000 in commercial leases for its three locations, unless the landlords agreed to discharge some of the liability as a favor, which is not expected. Exhibit 7.

ARGUMENT

I. Preliminary Injunction Standard

A plaintiff seeking a preliminary injunction must establish:

(a) a substantial likelihood of success on the merits;
(b) a substantial threat of irreparable harm if the injunction is not granted;
(c) that the threatened injury outweighs any damage that the injunction might cause the Defendants; and
(d) that the injunction will not disserve the public interest.

Planned Parenthood v. Sanchez, 403 F.3d 324, 329 (5th Cir. 2005). "A preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Sierra Club, Lone Star Chapter v. Federal Deposit Insurance Corp.*, 992 F.2d 545, 551 (5th Cir. 1993) ("at the preliminary injunction stage, the procedures in the district court are less formal, and the district court may rely on otherwise inadmissible evidence").

Because the "purpose of a preliminary injunction is to prevent irreparable injury to the parties and 'preserve the court's ability to render a meaningful decision on the merits,'" *Planned Parenthood of Hidalgo County v. Suehs*, 828 F. Supp.2d 872, 880 (W.D. Tex. 2012), the "relative position" to preserve is the federal Defendants not enforcing the Deeming Rule or any actions taken pursuant to it against Plaintiffs. *See Texans for Free Enter. v. Tex. Ethics Comm'n*,

732 F.3d 535, 536 (5th Cir. 2013) (affirming preliminary injunction against enforcement of a campaign contribution limit under Texas Election Code).

II. Plaintiffs Are Likely To Succeed In Establishing That TCA § 387a(b) Is Invalid

"To show a likelihood of success, the plaintiff must present a prima facie case, but need not prove that he is entitled to summary judgment." *Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.*, 710 F.3d 579, 582 (5th Cir. 2013).

The Supreme Court has twice held that statutes delegated legislative power to the Executive Branch in violation of the Constitution. *Panama Refining*, 293 U.S. at 433; *A.L.A. Shechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). While the Supreme Court has since found sufficient "intelligible principles" in other nondelegation challenges, *Panama Refining* and *Schechter* remain good and binding precedent illustrating that, in some statutes, Congress has gone too far. *See, e.g.*, *Whitman*, 531 U.S. at 474 (noting that "the requisite 'intelligible principle'" was "found … lacking" in *Panama Refining* and *Schechter*). Section 387a(b) of the TCA is another of these rare statutes, as demonstrated below.

a. Nondelegation standard

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. "This text permits no delegation of those powers[.]" *Whitman*, 531 U.S. at 472. At the same time, "the Constitution does not deny to the Congress the necessary resources of flexibility and practicality that enable it to perform its functions," and "Congress may obtain the assistance of its coordinate Branches—and, in particular, may confer substantial discretion on executive agencies to *implement* and *enforce* the laws." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (italics added; internal punctuation and citations omitted). "In a delegation challenge, the constitutional question is

whether the statute has delegated legislative power to the agency." *Whitman*, 531 U.S. at 912. "When Congress confers decisionmaking authority upon agencies *Congress* must 'lay down by legislative act an intelligible principle to which the person or body authorized to act is directed to conform.'" *Id.* (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)) (emphasis in original). Determining "whether Congress has supplied an intelligible principle … requires construing the challenged statute to figure out what task it delegates and what instructions it provides." *Gundy*, 139 S. Ct. at 2123.

Further, the Supreme Court has said that "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman*, 531 U.S. at 913 (contrasting discretion to define "country elevators," which are to be exempt from new-stationary-source regulations governing grain elevators, from "setting air standards that affect the entire national economy").

b. The TCA delegates to FDA the unbounded authority to leave any particular tobacco product unregulated, or to deem it to be subject to the TCA, in its absolute discretion.

The TCA is a comprehensive and burdensome regime with respect to any "tobacco products" subjected to it. When the statute was enacted in 2009, premium and nonpremium cigars, waterpipe tobacco (hookah), pipe tobacco, and other tobacco products were on the market and in widespread use. Still, Congress *itself* only applied the TCA to cigarettes and smokeless tobacco, leaving the Secretary the authority to impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. 387a(b). In other words, Congress left cigars, hookah, pipe tobacco, and all other tobacco products unregulated and punted the question whether to extend the TCA to the Secretary, without providing any parameters or guidance whatsoever. The statute does not require or even suggest a list of factors

the Secretary should consider; it does not establish a factual trigger and task the Secretary with "deeming" in the event he or she finds such facts to be present; and did not even include a broadly-stated policy aim, such that the Secretary shall deem a given product if doing so was judged to be beneficial to the "public interest" or similar aim.

Indeed, the *FDA itself* is on record stating that its deeming authority is not constrained by any policy parameters set by Congress. Defending itself against an APA challenge to the Deeming Rule in a sister court, the FDA wrote that "Congress authorized the FDA to subject 'any' tobacco product (except certain raw tobacco leaf) to the Tobacco Control Act as it 'deems' fit, without articulating any standards to cabin the agency's discretion." **Exhibit 14**, *Defs' Mem. in Opposition to Plfs' Mtns. for Summ. Judg. and in Support of Defs' Cross-Mtn. for Summ. Judg.*, filed in *Nicopure Labs, LLC v. Food and Drug Administration*, 266 F. Supp. 3d 360, 393 (D.D.C. 2017), *appeal docketed*, No. 17-5196 (D.C. Cir.); *see also id.* (FDA writing that "Congress's choice of the deferential word 'deems' *and the absence of any standard*—beyond the requirement that the product meet the definition of a 'tobacco product'—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion.") (emphasis added). The federal district court agreed with the FDA, recognizing that "the statute did not provide standards for when and how the agency was to exercise its discretion to deem[.]" *Nicopure Labs, LLC*, 266 F. Supp. 3d at 393.[20] The lack of any standard was also relied upon by FDA during the rulemaking process, in the course of rejecting commenters' suggestions that deeming ENDS should be deferred. FDA rejected the suggestion to defer, stating that it did not

[20] The *Nicopure* court made this statement in the course of holding that the only substantive limitation on the Secretary's deeming authority, and thus justiciable for purposes of Nicopure's APA challenge, is that deeming extends only to "tobacco products." 266 F. Supp. 3d at 393. Nicopure did not allege that the statute violates the nondelegation principle. To counsel's knowledge, the nondelegation doctrine has not been asserted in any other litigation involving the Deeming Rule.

have to "meet a particular public health standard to deem tobacco products." Deeming Rule, 81 Fed. Reg. at 28,983.[21]

c. This unbounded delegation of "deeming" authority violates the Constitution.

i. *Panama Refining Company v. Ryan*

Panama Refining Company v. Ryan involved a challenge to section 9(c) of the National Industrial Recovery Act (NIRA), dealing with "hot oil," or oil produced in excess of state allowances. 293 U.S. at 418. Congress "authorized" the President "to prohibit the transportation in interstate or foreign commerce" of petroleum products "produced or withdrawn from storage in excess of the amount permitted to be produced or withdrawn from storage by any State" law or regulation. *Id.* at 406. The Act was passed in June 1933, and less than a month later, President Roosevelt issued an executive order utilizing this authorization. The order prohibited transportation of oil produced or withdrawn in excess of state allowances, tracking the language of the statute. *Id.* at 405. Addressing the claim that the statute worked "an unconstitutional delegation of legislative power," the Court introduced the analysis as follows:

> The subject to which [the President's] authority relates is defined. It is the transportation in interstate and foreign commerce of petroleum and petroleum products which are produced or withdrawn from storage in excess of the amount permitted by state authority. Assuming for the present purpose, without deciding, that the Congress has power to interdict the transportation of that excess in interstate and foreign commerce, the question whether that transportation shall be prohibited by law is obviously one of legislative policy. Accordingly, we look to the statute to see whether the Congress has declared a policy with respect to that subject; whether the Congress has set up a standard for the President's action; whether the Congress has required any finding by the President in the exercise of the authority to enact the prohibition.

[21] This statement was also relied upon by the district court in *Nicopure*, in the course of holding that FDA was not required to accept any suggested regulatory alternatives under the APA. 266 F. Supp. 3d at 398; *see also id.* at 401 (holding that "[t]he statute does not limit the Secretary's authority to deem to when he finds it 'appropriate and necessary' to do so," and therefore there is "no source for a requirement that costs be taken into account when the deeming power is exercised")

293 U.S. at 414-15 (emphasis added). The Court examined the statute and found no such limits:

> Section 9(c) does not state whether or in what circumstances or under what conditions the President is to prohibit the transportation of the amount of petroleum or petroleum products produced in excess of the state's permission. It establishes no creterion to govern the President's course. It does not require any finding by the President as a condition of his action. The Congress in section 9(c) thus declares no policy as to the transportation of the excess production. So far as this section is concerned, it gives to the President an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit.

Id. at 415 (emphasis added).

Panama Refining distinguished NIRA § 9(c) from the provision upheld against a nondelegation challenge in *Field v. Clark*, 143 U.S. 649 (1892). That statute provided that, "'with a view to secure reciprocal trade' with countries producing certain articles," whenever the President ascertained that a country was imposing duties "'deem[ed] to be reciprocally unequal and unreasonable, he shall have the power and it shall be his duty,'" to issue a proclamation triggering the imposition of duties set out in the statute. 293 U.S. at 425 (quoting *Field, supra*, at 680). Because "'the suspension was *absolutely required* when the president ascertained the existence of *a particular fact*,'" the President was not making law but merely serving as the legislature's agent. *Id.* at 426 (quoting *Field, supra*, at 692-93) (emphasis added).[22]

While *Panama Refining* recognizes Congress's practical need for "flexibility and practicality" in order to function properly,[23] the Court also held that this recognition "cannot be

[22] In addition to setting out at least some kind of substantive standard, entirely lacking in the TCA, the statute considered in *Field* is also distinguishable because it overlaps with power regarding foreign affairs that is within President's own article II authority. *See Gundy v. United States*, 139 S. Ct. 2116, 2137 (2019) (Gorsuch, J., dissenting) (discussing line of cases involving delegations of discretion in matters "already within the scope of executive power").

[23] *Panama Refining*'s language acknowledging the need for appropriate delegation—that the Constitution "has never been regarded as denying to the Congress the necessary resources of flexibility and practicality, which will enable it to perform its function in laying down policies and establishing standards"—continues to be quoted in the Court's nondelegation opinions. *See, e.g.*, *Gundy*, 139 S. Ct. at 2123 (quoting *Yakus v. United States*, 321 U.S. 414, 425 (1944)).

allowed to obscure the limitations of the authority to delegate, if our constitutional system is to be maintained." *Id.* at 421. *Panama Refining* held that NIRA § 9(c) unconstitutionally delegated legislative power:

> As to the transportation of oil production in excess of state permission, the Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited.
>
> If section 9(c) were held valid, it would be idle to pretend that anything would be left of limitations upon the power of the Congress to delegate its lawmaking function.

293 U.S. at 430.

ii. TCA § 387a(b) is unconstitutional under *Panama Refining*.

Panama Refining, and the longstanding conception of "legislative" power common to all the Court's nondelegation jurisprudence, compel the conclusion that the TCA violates the nondelegation doctrine.

First, it is important to note that the statute declared unconstitutional in *Panama Refining* did not confer limitless authority on the President to regulate any industry in any way he saw fit. Instead, the Court began by observing that "[t]he subject to which this authority relates is defined. It is the transportation in interstate and foreign commerce of petroleum and petroleum products which are produced or withdrawn from storage in excess of the amount permitted by state authority." 293 U.S. at 415.

In the instant case, "[t]he subject to which" the challenged authority relates is the range of products meeting the TCA's definition of "tobacco products." This subject is itself even broader than the subject in *Panama Refining*, which at least was constrained to only a subset of petroleum products (those produced in excess of state-law limitations), defined in a way so as to

include only a subset of products that could be said to be especially problematic (in that they violated another extant legal standard, albeit under state law).

After acknowledging the limited subject matter at issue, *Panama Refining* held that "the question whether … transportation [of hot oil] shall be prohibited by [federal] law *is obviously one of legislative policy*." 293 U.S. at 415 (emphasis added). This holding reflects a principle that has animated the Court's nondelegation cases from *Field v. Clark* through *Gundy v. United States*: the authority to decide the factors or circumstances under which a given activity or product shall be subjected to a certain field of regulation is quintessentially one of legislative policy. In *Field*, the Court held that legislative power had not been delegated because Congress itself had established that the President must issue a proclamation if he ascertains that a covered country is imposing "reciprocally unequal and unreasonable" duties:

> As the suspension was absolutely required when the president ascertained the existence of a particular fact, it cannot be said that in ascertaining that fact, and in issuing his proclamation, in obedience to the legislative will, he exercised the function of making laws. Legislative power was exercised when congress declared that the suspension should take effect *upon a named contingency*.

143 U.S. at 693 (emphasis added). Similarly, *Gundy* only rejected the petitioner's nondelegation argument after interpreting the Sex Offender Registration and Notification Act (SORNA) "to *require* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*." 139 S. Ct. at 2123 (emphasis added). Gundy had argued that the operative provision "grants the Attorney General plenary power to determine SORNA's applicability to pre-Act offenders—to require them to register, or not, as she sees fit[.]" *Id.* The Court acknowledged that "[i]f that were so, we would face a nondelegation question," but avoided it by holding that SORNA did not grant such discretion.

By contrast, Congress unconstitutionally ceded legislative power when it vested the President with the authority to determine whether the transportation of hot oil should be prohibited by federal law without any guiding principles. *Panama Refining*, 293 U.S. at 415.

Following the fundamental understanding of legislative power illustrated in cases from *Field* through *Gundy*, the question whether this or that tobacco product, or all of them, or none of them, shall be regulated under the TCA "is obviously one of legislative policy." It was Congress's duty to establish a policy—imprinted in the statute in the form of factors, standards, even a broadly stated limiting principle—to guide the Executive Branch's discretion in determining what warrants "deeming" a product to be subject to the TCA's strictures. Instead, Congress failed to state "whether or in what circumstances or in what conditions" a product should be deemed, establish any criteria, or require any factual finding. *See* 293 U.S. at 415.

Indeed, this is a rare case in that the Defendants have already conceded the dispositive legal point. In its effort to avoid review under the APA—and fortuitously for the Plaintiffs here—the FDA has effectively admitted that the TCA cedes "an unlimited authority to determine the policy and to lay down the prohibition, *or not to lay it down*, as [the Secretary] may see fit." *See Panama Refining*, 293 U.S. at 415 (emphasis added). The Supreme Court held NIRA § 9(c) unconstitutional even though the statute expressly "declare[d] that a national emergency exists which is 'productive of widespread unemployment and disorganization of industry,'" *id.* at 416-17,[24] and the relevant authority was merely to prohibit the interstate transportation of certain commodities already illegal under state law, and which the President exercised less than a month after the NIRA became law. The deeming provision extends substantially further, granting the Executive Branch unchecked authority to regulate, *or not regulate*, a whole swath of products,

[24] *See also Panama Refining*, 293 U.S. at 443 (Cardozo, J., dissenting) (noting "[t]he statute was framed in the shadow of a national disaster").

without limitation to any subset of such products in violation of other law (or any other limitations), and FDA exercised that authority nine years after the TCA was enacted, deciding—in its infinite discretion—to regulate not only all those products Congress itself refused to regulate, but also an entirely new industry of products that are materially different. Much more than a mere definition of "country elevators," an entire industry—or at least an entire nation's worth of small businesses in the industry, including Big Time Vapes and the USVA's members—are threatened with extermination pursuant to the FDA's unilateral policy choice. Affected businesses have no avenue for challenging the application of the TCA to their industry or business, *precisely because* the TCA lacks any substantive standard. *Cf. American Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946) (noting, after finding a sufficiently limiting principle, that "[p]rivate rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations"); *Yakus*, 321 U.S. at 426 ("The standards prescribed by the present Act, with the aid of the 'statement of the considerations' required to be made by the Administrator, are sufficiently definite and precise to enable Congress, the courts and the public to ascertain whether the Administrator, in fixing the designated prices, has conformed to those standards.").

The deeming provision therefore violates the principle of nondelegation under *Panama Refining* and, unlike in *Gundy*, there is no way to save the statute by interpreting § 387a(b) as if it *required* all, or any, tobacco products to be "deemed."

d. The FDA's authority will be inapposite.

In response, FDA will seek to rescue the statute by pointing to the fact that broad delegations have been upheld by the Court for decades, and that the TCA passes muster because

deeming authority is circumscribed within the field of "tobacco products." Neither of these arguments can save the TCA's unchecked deeming authority.

i. FDA cannot seek refuge in precedent upholding broadly-worded "intelligible principles" where TCA § 387a(b) incorporates *no* principle.

Defendants will make repeated and strenuous reference to the fact that, as observed most recently in *Gundy*, the Court has "over and over upheld even very broad delegations." 139 S. Ct. at 2129. This is true enough, but cases and controversies are not decided based on generalities.

Defendants can point to no case upholding a statute like the TCA's deeming provision. Every case rejecting a nondelegation argument has done so only because—broad as it may be—the statute at issue incorporates some limiting principle beyond the fact that the authority operates within a given field of activity. For example, *Gundy* cites cases upholding delegations to regulate "in the 'public interest,'" id. at 2129 (citing *National Broadcasting Co. v. United States*, 319 U.S. 190, 216 (1943), and *New York Central Securities Corp. v. United States*, 287 U.S. 12, 24 (1932)), "authorizations for agencies to set 'fair and equitable' prices and 'just and reasonable' rates," id. at 2129 (citing *Yakus v. United States*, 321 U.S. 414, 422 (1944), and *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944)), and "a delegation to an agency to issue whatever air quality standards are 'requisite to protect the public health,'" id. (citing *Whitman*, 531 U.S. at 472). These cases are among those most frequently cited as representing the outer bounds of permissible delegations under current law. *See, e.g.*, *Loving v. United States*, 517 U.S. 748, 772 (1996) (citing *NBC*); *Whitman*, 531 U.S. at 474 (citing *NBC* and *Yakus*, among others); *United States v. Whaley*, 577 F.3d 254, 263-64 (5th Cir. 2009) (citing *NBC*, *Yakus*, and *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

Thus, even the most extreme examples of upheld delegations included some basic standard manifesting Congressionally-determined policy and limiting the agency's discretion.[25]

ii. The fact that the Secretary's deeming authority is limited to the field of "tobacco products" does not substitute for the required "intelligible principle."

Acknowledging, as they must, that there are no standards or principles limiting the Secretary's discretion to deem—or not to deem—any given tobacco product, Defendants may argue that the mere fact that this authority operates only within the field of "tobacco products" is sufficient to save the statute. This argument is meritless.

As already noted above, *Panama Refining* began its analysis by recognizing that "[t]he subject to which [the President's] authority relates is defined" as the narrow field of oil produced in violation of the limits allowable under state law and regulations. 293 U.S. at 414-15. The statute was nonetheless unconstitutional because it gave the President the authority to prohibit that transportation, or not prohibit it, without laying down any principles or standards to guide his discretion. Every delegation case involves a delegated task that operates within a certain field of activity; resolution of the case requires determining "what task it delegates and *what instructions it provides*." *Gundy*, 139 S. Ct. at 2123 (emphasis added). If the fact that the deeming authority was limited to the field of "tobacco products" was sufficient in and of itself, then *Gundy*, and all other nondelegation cases, would have been much easier for the Court to dispatch by simply noting that the authority only operates within the field at issue. For example, in *Gundy*, while the challenged authority was circumscribed within the narrow field of "sex

[25] While the deeming provision is so standardless that it fails even the permissive review called for under the Court's current jurisprudence, Plaintiffs note that the current standard applied by courts is unduly permissive and the nondelegation doctrine should be more vigorously enforced by the judiciary, as required by the structural principles of the Constitution. *See Gundy*, 139 S. Ct. at 2131 (Gorsuch, J., dissenting). While the district court need not wade into that debate, because Plaintiffs prevail under current law, Plaintiffs note that argument solely for purposes of Supreme Court review.

offenders" as defined in the statute, *id.* at 2122 (acknowledging SORNA's "sex offender" definition), the separation of powers required the Court to analyze whether Congress had sufficiently limited the Attorney General's discretion to determine SORNA's applicability to pre-Act offenders, *id.* at 2123.

III. Irreparable Harm

Plaintiffs must show that they are "'likely to suffer irreparable harm,' that is, harm for which there is no adequate remedy at law." *Daniels Health Sciences, L.L.C.*, 710 F.3d at 585. Plaintiffs will soon suffer severe injury that qualifies as irreparable for at least two reasons, each of which is independently sufficient: (1) even if they prevail on the merits at trial or on summary judgment, Plaintiffs cannot recover monetary damages against the federal government to compensate them for their imminent, severe financial losses; and (2) the consequences of the Deeming Rule and its enforcement are such that Plaintiffs will literally go out of business.

a. Plaintiffs' injury is irreparable because damages are not recoverable against the federal government.

"The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm," but "[t]he absence of an available remedy by which the movant can later recover monetary damages … may also be sufficient to show irreparable injury." *Enterprise Intern., Inc. v. Corporacion Estatal Petrolera Ecuatoriana*, 762 F.2d 464 (5th Cir. 1985) (citing, inter alia, *Ohio Oil Co. v. Conway*, 279 U.S. 813, 815 (1929)). *See, e.g.*, *Toomer v. Witsell*, 334 U.S. 385, 392 (1948) (plaintiff shrimp fishermen established irreparable injury from state tax law because it required payment of tax with no apparent means of recovery, and "withdrawal from further fishing" until the issue could be litigated in state courts "would have resulted in a substantial loss of business for which no compensation could be obtained"); *Ohio Oil Co.*, 279 U.S. at 257

(irreparable injury because no remedy to reclaim taxes paid during pendency of suit). "Indeed," the Fifth Circuit has noted, "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Texas v. U.S. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring in part and in the judgment)) (emphasis in original). Further, "[w]hen determining whether injury is irreparable, 'it is not so much the magnitude but the irreparability that counts[.]'" *Id.* (quoting *Enter. Int'l*, 762 F.2d at 472).

Plaintiffs here have no hope of securing monetary relief in this case due to the government's immunity from damages; their damages are therefore irreparable. *Texas*, 829 F.3d at 433; *Kentucky v. U.S. ex rel. Hagel*, 759 F.3d 588, 599 (6th Cir. 2014); *Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994); *Johnson v. United States*, EP-14-CV-00317-DCG, 2014 WL 12540469, at *7 (W.D. Tex. Sept. 12, 2014) **(**stating that Plaintiffs have shown irreparable harm when statutory bar required arbitration process, which did not allow monetary relief, prior to filing suit in federal court and gaining preliminary injunction). As the District Court for the District of Columbia noted in a suit against FDA, "[w]here a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by [the] plaintiff is irreparable *per se*." *Smoking Everywhere, Inc. v. United States FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (quoting *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008), and enjoining FDA from barring the importation of vapor products into the United States as unapproved new drugs or medical devices).

While the magnitude of these financial losses will be severe, establishing the precise estimated dollar loss is not dispositive, because the material factor is not the magnitude but the

fact that the losses would be unrecoverable in the ordinary course of litigation. *Texas*, 829 F.3d at 433-34.

The looming PMTA deadline and the imminent change to the FDA's enforcement policy to accelerate enforcement against flavored products each independently present a threat of irreparable injury.

i. Injury from revised flavor policy

Secretary Azar declared on September 11 that "all flavored e-cigarettes, other than tobacco flavor, would have to be removed from the market" approximately 30 days after FDA finalizes the revised policy. Exhibit 6. On September 20, FDA stated that it "intend[s] to finalize [this] compliance policy in the coming weeks." Exhibit 16. Thus, the policy could be issued by FDA any day now. Flavored products that will effectively be banned from the market by this revised policy comprise 90-98% of sales of vape shops, as reflected by the attached declarations of seven USVA members. Every declarant affirms that he or she will have no choice but to sell out current inventory and close his or her retail shop, whether the shop is a manufacturer or only sells e-liquids manufactured by others.[26] Destroying these shops will, of course, have cascading economic consequences, including removing dozens of individuals from employment, destroying the personal investments of the owners, and removing what for most of them is their sole source of income, requiring them to find other work after having dedicated years to their businesses. Several USVA members attest that they will even be forced into personal bankruptcy.

While any amount of financial damage is irreparable here, these damages cannot be any more severe, and federal courts have granted injunctions against government defendants in far

[26] Only Smax International, LLC, a manufacturer with overseas sales, could possibly survive.

less dire circumstances. *American Trucking Associations, Inc. v. Gray*, 483 U.S. 1306 (1987) (irreparable injury from "substantial economic losses" if trucking companies are forced to pay state tax with no means of securing refund after appeal); *Toomer*, 334 U.S. at 392; *Texas*, 829 F.3d at 434 ("Here Petitioners have raised threatened harms—including unemployment and the permanent closure of plants—that would arise during the litigation is a stay is not granted, that are irreparable, *and* that are great in magnitude.") (emphasis in original); *Johnson, supra*, at *7 (irreparable injury where plaintiff "was unsure if he would reduce his base salary but … would definitely lose out on the bonus" "ranging from $75,000 to $200,000" annually).

ii. Injury from PMTA requirements

Application of the TCA's premarket review requirement means that any of Plaintiffs' products not the subject of a costly PMTA submitted by the PMTA deadline will be illegal for marketing in the United States. The costs of attempting compliance with the PMTA requirements would be so burdensome that—by the FDA's own admission—it would prompt "considerable product consolidation and [market] exit." RIA, AR 23,989-90 (FDA itself assuming that "54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids [would] not submit a marketing application and will exit the market after the initial compliance period … ends."). In other words, the FDA itself estimates that more than half the delivery systems on the market, and a large majority of e-liquids, would be discontinued because even attempting to comply with the TCA's requirements is prohibitively expensive.

This would have a devastating impact on Plaintiffs' businesses. Even if a business could find a way to do the impossible and submit a PMTA sufficient for filing—despite the fact FDA still has not even finalized the list of HPHCs for which testing is required—conducting *any* manner of testing, and paying lawyers and consultants to prepare the PMTA, would drain

substantial resources. These compliance costs alone constitute irreparable injury. *Texas*, 829 F.3d at 433 (costs of complying with emission control requirements); *Cigar Assoc. of America v. U.S. Food and Drug Admin.*, 317 F. Supp. 3d 555, 563 (D.D.C. 2018) (costs of conforming to packaging requirements under Deeming Rule constitutes irreparable injury for cigar companies). Then, assuming a manufacturer achieved the impossible and submitted a complete PMTA for review, it could not possibly submit PMTAs for all products, thereby prohibiting the marketing of any of its current products for which a PMTA is not submitted by the deadline. The lost sales attributable to the loss of part of Plaintiffs' product lines alone constitute irreparable injury. *Toomer*, 334 U.S. at 392 (threatened substantial loss of business).

b. Plaintiffs' injury is irreparable because the challenged law threatens the very existence of many of their businesses.

The Fifth Circuit also recognizes that financial loss can be irreparable "where the loss threatens the very existence of the movant's business." *Texas*, 829 F.3d at 434 (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)); *Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.*, 875 F.2d 1174, 1179 (5th Cir. 1989). *See Smoking Everywhere, Inc.*, 680 F. Supp. 2d at 76 ("Smoking Everywhere and NJOY represent that the inability to import their electronic cigarettes into the United States … will deprive them of needed revenue and thus threaten the continued viability of their respective enterprises. I agree."). In the absence of injunctive relief, the revised enforcement policy will destroy the Plaintiffs' businesses.

Even aside from the flavor policy, they will also likely be unable to survive after the PMTA deadline arrives, because they cannot afford to submit PMTAs for a single product, much less all their products. Even if they could afford PMTAs, there is no hope of submitting complete and satisfactory PMTAs, as discussed above. While this threat from the PMTA requirement is less imminent than the threat from the revised flavor policy, Plaintiffs will be

irreparably damaged by the PMTA requirement well before the submission deadline in May 2020, because they must begin paying lawyers and consultants and labs *now* in an attempt to assemble what they can in order to have something to submit by the deadline.

IV. Public Interest

In many cases involving challenges to statutes and government policies, the balance of harms and public interest inquiries are particularly interrelated. It is helpful here to discuss the public interest prong first, and then conclude with a discussion of the balance of harms.

The government has no legitimate interest in exercising power inconsonant with the Constitution's structure. As another federal district court recently found in a separation of powers case, "it is [n]ever in the public interest for the Constitution to be violated." *Ironridge Glob. IV, Ltd. v. Sec. & Exch. Comm'n*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015) (issuing preliminary injunction against SEC enforcement action in appointments clause challenge). The separation of powers is part of the "constitutional structure of our Government that protects individual liberty," *Bond v. United States*, 564 U.S. 211, 223 (2011) (discussing standing on the part of individuals, not just government agencies or departments, to assert violations of the separation of powers), and, therefore, preservation of such principles should weigh heavily in the balancing of interests. *See Mistretta v. United States*, 488 U.S. 361, 380 (1989) (citations omitted) ("This Court consistently has given voice to, and has reaffirmed, the central judgment of the Framers of the Constitution that, within our political scheme, the separation of governmental powers into three coordinate Branches is essential to the preservation of liberty."). The Fifth Circuit recently observed that, "[o]rdinarily, of course, the protection of constitutional rights *would* be the highest public interest at issue in a case." *Defense Distributed v. United States Dep't of State*, 838 F.3d 451, 458 (5th Cir. 2016) (italics in original). While the Court

found that such interests were outweighed in that case by the "very strong interest in national defense and national security," no such interest is present here, and the "ordinary" rule—valuing constitutional interests above the (likely) unconstitutional exercise of power—applies. Therefore, regardless of the particular interest the Defendants claim is served by its Deeming Rule, the public interest in preserving the separation of powers prevails.

The public interest weighs decisively in favor of Plaintiffs for additional reasons. First, even if the Court considers the strength of the public interests asserted by Defendants here on their merits, the Defendants' statements and actions respecting the Deeming Rule and its enforcement reflect their own equivocation as to which public health interest should take precedence. Traditional cigarettes result in the premature deaths of nearly half a million Americans every year.[27] Former Commissioner Gottlieb consistently recognized that "what primarily causes death and disease from tobacco use isn't the nicotine … *[i]t's the act of lighting tobacco on fire* to free that drug for inhalation." *E.g.*, Exhibit 2. This acknowledgment of the acute danger of combustible tobacco products was, in fact, the "central animating principle" of the FDA's approach to tobacco regulation, as stated in September 2018, as FDA recognized that "[e]-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products[.]" *Id.* The Deeming Rule itself recognizes that "the availability of alternatives to traditional tobacco flavors in some products (e.g., ENDS) may potentially help some adult users who are attempting to transition away from combusted products," and FDA expressly built in the "staggered" compliance policy, delaying enforcement against ENDS products, in an effort to balance "concerns regarding flavored tobacco products' appeal to youth"

[27] U.S.FOOD AND DRUG ADMINISTRATION, *Center for Tobacco Products Overview*, https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/center-tobacco-products-overview (last visited Oct. 10, 2019).

with "emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use." 81 Fed. Reg. at 28,977. Thus, while recognizing competing interests, the FDA's express rationale—at that time and for long after—was to avoid clearing ENDS from the market by hasty regulation, and this is precisely why the FDA extended the PMTA deadline all the way to 2022 in its August 2017 Guidance. Exhibit 17 at 5. Again, in June 2019, FDA opposed the plaintiffs' request in the Maryland case to accelerating the PMTA deadline to a mere four months after the district court's order, *citing the public interest in maintaining ENDS products on the market*:

> Mass market exit of such products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products. Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products, even if particular ENDS products ultimately receive marketing authorization and return to the market later. And, although there has been great recent progress in declining use of cigarettes for all age groups, I am concerned that these declines could be slowed or reversed in the case of a very sudden and very dramatic reductions in availability.

ECF No. 120-1 (Decl. of Mitchell Zeller, Director, Center for Tobacco Products, U.S. FDA), *American Academy of Pediatrics v. U.S. FDA*, 8:18-cv-00883-PWG (emphasis added). Granting the injunction will prevent the "mass market exit" and "serious risk" that concerns the FDA's own expert, at least until a decision on the merits can be entered.

Defendants will attempt to distance themselves Mr. Zeller's warnings as stated just four months ago, and this leads to the second point: it is inappropriate to give much weight to the interests asserted to be paramount by these Defendants when it is *their very authority*—apart from Congress—to dictate what interests support "deeming" tobacco products to be subject to regulation that is *at the heart of the case*. In granting the stay of the FDIC's order pending review of the appointments clause challenge, the Fifth Circuit found that "the public interest …

does not weigh against a stay" because, in part, "the constitutionality of the structure of the fact-finding procedure on which the FDIC relies lies at the heart of this motion." *Burgess*, 871 F.3d at 304. Similarly, the constitutionality of these Defendants' authority to decide where the public interest lies regarding regulation of "tobacco products" is the precise issue in this case.

V. Balance of Harms

The injury Plaintiffs will suffer if preliminary relief is denied far outweighs any potential injury to the government from issuance of an injunction.

If the Plaintiffs do not get an injunction pending trial on the merits, the damage will be severe, permanent, and irreparable. Big Time Vapes and many other USVA members will be forced to close, business owners will irretrievably lose their investments and stream of income, and employees will lose their jobs. Even if Plaintiffs prevail on the merits, these damages cannot be undone or compensated. On the other hand, preliminarily enjoining the exercise of authority under § 387a(b) of the TCA would only temporarily delay Defendants' enforcement until the merits can be decided. *See Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1305 (2010) (Scalia, J., in chambers) ("Refusing a stay may visit an irreversible harm on applicants, but granting it will apparently do no permanent injury to respondents.").

This temporary delay in enforcement is contrasted with other cases in which granting preliminary relief can cause permanent damage to the Defendants' interests. *Cf. Defense Distributed*, 838 F.3d at 460 (noting that, if preliminary injunction is granted and plaintiffs are permitted to post weapons files online, making them available to foreign enemies in perpetuity, "a preliminary injunction would function, in effect, as a permanent injunction as to all files released in the interim," and "the national defense and national security interest would be harmed forever").

VI. Request to Waive Bond

"Despite the apparently mandatory language of Rule 65(c), the Fifth Circuit has held that a court, in the proper exercise of its discretion, 'may elect to require no security at all' in an appropriate case. *Gordon v. City of Houston, Tex.*, 79 F. Supp. 3d 676, 695 (S.D. Tex. 2015) (quoting *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996)). This is an appropriate case because, just as in *Gordon*, there is no risk of monetary loss to the Defendants if the injunction issues. Plaintiffs request that the Court waive the requirement of bond.

PRAYER

For the foregoing reasons, and for any further reasons appearing after any hearing on this motion, Plaintiffs respectfully request that the Court preliminarily enjoin Defendants from exercising any authority over any "tobacco products" deemed to be subject to the TCA pursuant to Defendants' power under § 387a(b) of the TCA, including, but not limited to, the current Deeming Rule and any enforcement of same.

Respectfully submitted,

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Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that the foregoing memorandum in support of the motion for preliminary injunction will be served by personal delivery upon the Defendants listed below as soon as possible. Further, Plaintiffs' counsel Jerad Najvar emailed Mr. Eric Beckenhauer, an attorney with the Federal Programs Branch of the U.S. Department of Justice, and who currently represents Defendants in other Deeming Rule litigation, on October 3 to notify him of this forthcoming motion. Mr. Najvar and Mr. Beckenhauer have been in periodic communication by email since that date. A courtesy copy of all documents will be emailed to Mr. Beckenhauer immediately upon filing of same.

By personal delivery:

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Norman E. Sharpless, M.D., in his official capacity as
Acting Commissioner for Food and Drugs
10903 New Hampshire Avenue
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Alex M. Azar, II in his official capacity as Secretary of U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Courtesy copy by email on October 10, 2019:

Eric B. Beckenhauer
Assistant Director
U.S. Department of Justice
Civil Division, Federal Programs Branch
eric.beckenhauer@usdoj.gov

/s/ Spencer M. Ritchie
SPENCER M. RITCHIE